DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

August 28, 2014

Zimmer Surgical, Incorporated
C/O Mr. Michael T. Wolford
Regulatory Affairs Specialist
200 West Ohio Avenue
Dover, OH 44622

Re: K142166
Trade/Device Name: TotalShield Surgical Helmet System
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: II
Product Code: FYA
Dated: July 17, 2014
Received: July 30, 2014

Dear Mr. Wolford:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith -S

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K142166

Device Name
TotalShield Surgical Helmet System

Indications for Use *(Describe)*

The TotalShieldTM Zippered Surgical Toga and/or TotalShieldTM Surgical Hood is for use with the TotalShieldTM Surgical Helmet and/or TotalShieldTM Advanced Surgical Helmet with LED lighting as the TotalShieldTM Surgical Helmet System that is intended to be worn by surgical personnel to provide a barrier between the operating environment and the surgical personnel in order to protect against contamination and/or exposure of infectious body fluids and harmful microorganisms.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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200 West Ohio Avenue
Dover, Ohio 44622
330.343.8801

510(k) Summary of Safety and Effectiveness

510(k) Summary

Sponsor:	Zimmer Surgical, Inc. 200 West Ohio Avenue Dover, OH 44622 Phone: (330) 343-8801
Contact:	Michael T. Wolford Regulatory Affairs Specialist Phone: (330) 364-9411
Date:	July 17, 2014
Trade Name:	*TotalShield*^{TM} Surgical Helmet System
Product Code/Device:	FYA – Gown, Surgical
Regulation Number and Description:	21 CFR 878.4040 – Surgical Apparel
Predicate Device	*TotalShield*^{TM} Surgical Helmet System K132386, cleared December 23, 2013.
Device Description	The *TotalShield*^{TM} Surgical Helmet System is comprised of the *TotalShield*^{TM} Zippered Surgical Toga, *TotalShield*^{TM} Surgical Hood, *TotalShield*^{TM} Surgical Helmet and Advanced Surgical Helmet with LED lighting and various accessories. The *TotalShield*^{TM} Zippered Surgical Toga and/or *TotalShield*^{TM} Surgical Hood are used with the *TotalShield*^{TM} Helmet and/or *TotalShield*^{TM} Advanced Surgical Helmet with LED lighting as the *TotalShield*^{TM} Surgical Helmet System to provide a barrier between the operating environment and the surgical personnel in order to protect against contamination and/or exposure of infectious body fluids and harmful microorganisms. The *TotalShield*^{TM} Surgical Helmet and Advanced

Surgical Helmet with LED lighting have a battery powered fan, which provides a continuous flow of air in the *TotalShield*™ Surgical Hood or Zippered Surgical Toga.

The *TotalShield*™ Surgical Hood is a stand-alone head cover that may be worn with a separate surgical gown, while the *TotalShield*™ Zippered Surgical Toga is a one-piece head and body cover.

The stand-alone *TotalShield*™ Surgical Hood is identical to the hood that is incorporated into the *TotalShield*™ Zippered Surgical Toga. The *TotalShield*™ Surgical Hood or Zippered Surgical Toga must be worn over a *TotalShield*™ Surgical Helmet or Advanced Surgical Helmet with LED lighting.

The *TotalShield*™ Zippered Surgical Toga has been tested to meet the applicable AAMI PB70 standards for level 4 compliance. The AAMI standard does not cover apparel for the head, face, and eyes. Therefore, the hoods and lens are exempt from classification under the AAMI PB70:2003 standard.

Intended Use:

The *TotalShield*™ Zippered Surgical Toga and/or *TotalShield*™ Surgical Hood is for use with the *TotalShield*™ Surgical Helmet and/or *TotalShield*™ Advanced Surgical Helmet with LED lighting as the *TotalShield*™ Surgical Helmet System that is intended to be worn by surgical personnel to provide a barrier between the operating environment and the surgical personnel in order to protect against contamination and/or exposure of infectious body fluids and harmful microorganisms.

Technological Characteristics

The TotalShield Surgical Helmet System is substantially equivalent to the predicate device in that the devices have the same technological characteristics, including:

- Has the same intended use, target population and indications for use as the predicate
- Uses the same operating principles
- Incorporates the same basic design of durable helmet and single-use hoods and togas
- Hood and toga are sterilized using the same mode
- Both are sterilized to SAL 10^{-6}
- Reusable helmets are provided non-sterile
- Is manufactured of similar materials

Comparison to Predicate: The *TotalShield*™ Surgical Helmet System is substantially equivalent to the legally marketed predicate device, *TotalShield*™ Surgical Helmet System, in that these devices have the same intended use and are similar in design. The following tables provide a comparison between the predicate device and modified device:

Property	Predicate: *TotalShield*™ Surgical Helmet System	Modified Device: *TotalShield*™ Surgical Helmet System
Intended Use	The TotalShield™ Zippered Surgical Toga and /or TotalShield™ Surgical Hood is for use with the TotalShield™ Surgical Helmet and/or TotalShield™ Advanced Surgical Helmet with LED Lighting as the TotalShield™ Surgical Helmet System that is intended to be worn by surgical personnel to provide a barrier between the operation environment and the surgical personnel in order to protect against contamination and/or exposure of infectious body fluids and harmful microorganisms.	Same
Target Population	Operating Room Personnel	Same

Materials of Construction

Property	Predicate: *TotalShield*™ Surgical Helmet System K132386	Modified Device: *TotalShield*™ Surgical Helmet System
Toga and Hood	SMS nonwoven fabric	BVB nonwoven fabric
Lens/Face Shield	PETG Clear Copolyester	Same
Filter	Blended Synthetic Fiber Spunbound Polypropylene	Same
Helmet	Plastic	Same
LED Components	Aluminum, Stainless Steel	Same

Technology and Product Features

Property	Predicate: *TotalShield*™ Surgical Helmet System	Modified Device: *TotalShield*™ Surgical Helmet System
***TotalShield*™ Zippered Surgical Toga and Hood**		
Operating Principle	The *TotalShield*™ Zippered Surgical Toga has been designed to properly fit the *TotalShield*™ Surgical Helmet and Advanced Surgical Helmet with LED Lighting in order to be used together as the *TotalShield*™ Surgical Helmet System. The *TotalShield*™ Zippered Surgical Toga or Surgical Hood is fastened to either the *TotalShield*™ Surgical Helmet or Advanced Surgical Helmet with LED Lighting with aid of hook-and-loop fasteners and mechanical slot. The device acts as a barrier between the operating environment and the surgical personnel.	Same
Adjustable Length (Toga)	Tear away feature (12” from length)	Same

Consensus Standards	Level 3 Barrier Performance AAMI/ANSI PB70:2003/(R)2009 ASTM F2407-06 Standard Specification for Surgical Gowns Intended for Use in Healthcare Facilities	Level 4 Barrier Performance AAMI/ANSI PB70:2003/(R)2009 ASTM F2407-06 Standard Specification for Surgical Gowns Intended for Use in Healthcare Facilities
Sterility Assurance Level	10^{-6}	Same
Condition of Use	Single Use/Disposable	Same
Closure	Toga Neck tie/waist tie Hood pull over	Same
Toga Sizes	Regular, Large, Extra Large	Same
Color	Blue	Same
***TotalShield*™ Surgical Helmet and Advanced Surgical Helmet with LED Lighting**		
Method of Hood Attachment	Mechanical slot and hook-and-loop	Same
Lighting Option	LED	Same

Performance Comparison

Property or Characteristic	Testing Method	Predicate: *TotalShield*™ Surgical Helmet System	Modified Device: *TotalShield*™ Surgical Helmet System
***TotalShield*™ Zippered Surgical Toga and Surgical Hood**			
Flammability of Clothing Textiles	ASTM F2100-07 reference 16 CFR-1610.4	Class 1 Compliant-pass	Class 1 Compliant-pass

Biological Evaluation on Skin Contact	ISO-10993-10 Intracutaneous Reactivity Test ISO-10993-5 MEM Elution Assay with L-929 Mouse Fibroblast Cells ISO-10993-10 Guinea Pig Maximization Sensitization Test	Compliant- pass	Compliant- pass
Sterility Method	ISO 11607-2 Packaging Validation ISO 11135-1 EO Validation ISO 10993-7 EO Residual Test	Compliant- pass	Compliant- pass
Tear Resistance	ASTM D5733 MD Trap Tear Compliant- pass AAMI Level 3	Compliant- pass	Compliant- pass
Tensile Strength	ASTM D5034 Grab Tensile Strength	Compliant- pass	Compliant- pass
Seam Strength	ASTM D1683	Compliant- passed seam test	Compliant- passed seam test
Lint	ISO 9073; EN 13795-2 Test methods for surgical drapes, gowns and clean air suits, used as medical devices for patients, clinical staff and equipment	Compliant- pass	Compliant- pass
Water Vapor Transmission Rate	ASTM E96 with Water	Compliant- pass	Compliant- pass
Water resistance: Impact penetration Hydrostatic pressure	AAMI/ANSI PB70	Compliant Level 3	Compliant Level 4
***TotalShield* Surgical Helmet and Advanced Surgical Helmet with LED Lighting**			
Airflow Testing	Internal Fan Performance Test Method	Pass Acceptance Criteria	Pass Acceptance Criteria
Helmet Noise Testing	Internal Noise Measurement Test Method	Pass Acceptance Criteria	Pass Acceptance Criteria
Battery Life Testing	Internal Battery Performance Test Method	Pass Acceptance Criteria	Pass Acceptance Criteria

Non-Clinical Performance Description:	During the design and development of the *TotalShield*™ Surgical Helmet System, the following tests were completed: Electrical safety and Environmental testing (IEC 60601-1 and IEC 60601-1-2) Device Usability testing was conducted in accordance with requirements of IEC 60601-1-6 and IEC 62366:2007. Sterilization Validation testing was conducted in accordance with AAMI/ANSI/ISO 11607-1, 11607- 2 and AAMI/ANSI/ISO 11135-1. Shipping Validation was conducted according to ASTM D4169-09. Biocompatibility Testing was conducted on skin contact material in accordance with ISO 10993-1, ISO 10993-10, ISO 10993-5 and ISO 10993-7. Non-Clinical testing was conducted to demonstrate that the subject device performed as intended and met all acceptance criteria, including: • Airflow Testing • Helmet Noise Testing • Battery Life Testing • Liquid Barrier testing (per AAMI/ANSI PB70 Level 4, for Surgical Zippered Toga only) The *TotalShield*™ Surgical Helmet System adheres to the specifications for requirements for performance, documentation, and labeling per ASTM F2407-06.
Clinical Performance	No Clinical evaluations necessary for this device
Conclusion	All tests passed according to predetermined acceptance criteria, thus demonstrating equivalent performance of the subject device to the predicate device.